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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,994

07/14/2003

Scott Cunningham

2848

5963

50855

7590

03/27/2009

Tyco Healthcare Group LP
60 MIDDLETOWN AVENUE
NORTH HAVEN, CT 06473

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/618,994	Applicant(s) CUNNINGHAM ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-17 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-17 and 20-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 12/18/2008.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite that the trapezoidal transverse cross-section includes exactly four sides. However, the only disclosure the applicant provides is a "general trapezoidal configuration" (abstract, paragraphs 6 and 22), and is silent as to exactly how many sides are in the trapezoidal transverse cross-section. It is noted that a "general trapezoidal configuration" may include more than four sides as long as the resulting shape is similar to a trapezoid.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 5-6, 8, 10-17, and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by **McGregor et al.** (U.S. Patent No. **5,002,564**).

Claims 1-2, 5-6, 8, 10-17, and 21-22: McGregor et al. disclose a surgical needle, which comprises an elongated needle body curved along a longitudinal y axis, and comprising x and z axes transverse to the y-axis, the elongated needle body including a central shaft **25** and having a first end **30** for attachment to a suture and a second needle end for penetrating tissue, the needle end including planar lower **14** and upper **16** opposed surfaces and single side surfaces **20a-b** extending continuously between the lower and upper surfaces and contiguous therewith, the upper surface and side surfaces intersecting to define opposed first and second generally arcuate side cutting edges **16** or **18** extending to a pointed tip **12**, the lower surface extending to a linear third cutting edge **T** defined at the intersection of the side surfaces and proximal of the pointed tip, the third cutting edge extending in oblique relation relative to the longitudinal axis of the needle body to terminate at the pointed tip, the third cutting edge intersecting the upper planar surface at an angle ranging from 15 to 30 degrees relative to the longitudinal axis (col. 2, lines 58-65), the second needle end defining a maximum dimension inclusive of the first and second cutting edges greater than a corresponding

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maximum dimension of the central shaft, the second needle end having a transition area, a proximal portion of the needle end disposed proximally of the transition area including a first length having a trapezoidal transverse cross-sectional dimension length (Figure 6) inclusive of the first and second cutting edges and a distal portion of the needle end disposed distally of the transition area including a second length having a triangular transverse cross-sectional dimension (Figure 5) inclusive of the first and second cutting edges, the first length being longer than the second length, at least a portion of the first length having a diameter that decreases distally towards the needle end, and at least a portion of the first length having a diameter that decreases proximally towards the central shaft of the needle body (see Figures 1-8).

McGregor et al. disclose the elongated needle shaft defining an angle of curvature ranging from about 80 degrees to 180 degrees (Figure 3).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 7, 9, 20, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over by **McGregor et al.** (U.S. Patent No. **5,002,564**).

Claims 7, 9, 20, and 23-26: McGregor et al. do not expressly disclose the first width or width of the trapezoidal cross section or maximum dimension of the second needed

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end being not less than about 1.5 times the shaft width, or the first height, or height of the trapezoidal cross section being not greater than about 0.5 times the shaft height.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the first width being not less than about 1.5 times the shaft width, or the first height being not greater than about 0.5 times the shaft height, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

In addition, McGregor et al. do not expressly disclose that the trapezoidal transverse cross-section includes exactly four sides or the triangular transverse cross-section includes exactly three sides, since there are extra sides or "fluted edges" **18a-b** (five sides in the triangular cross-section and six sides in the trapezoidal cross-section) that give the needle its thickness as seen in Figures 5-6. However, McGregor et al. do recognize that at the wider portion of the needle, there are six sides, and at the tapered end of the needle, there are only five sides which enable better tissue penetration, as well as a smaller wound area (col. 3, lines 15-20). The extra sides or fluted edges are only present to create thickness and to further improve tissue penetration (col. 3, lines 21-24). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the desirable number of sides trapezoidal transverse cross-section with exactly four sides or the triangular transverse cross-section with exactly three sides, depending on the desired thickness (a tapered portion may require fewer sides,

as mentioned by McGregor et al. above) and as long as the needle facilitates better tissue penetration, as well as a smaller wound area.

Response to Arguments

7. Applicant's arguments filed 12/18/2008 have been fully considered but they are not persuasive.

8. Applicant generally argues that McGregor et al. do not disclose either a trapezoidal transverse cross-section or a triangular transverse cross-section, because as seen in Figures 5-6, the triangular transverse cross-section has five sides instead of three and the trapezoidal transverse cross-section has six sides instead of four, and that since the extra sides improve ease of tissue penetration, minimized tissue distortion, and minimized wound trauma and therefore McGregor teaches away from using a three-sided triangular transverse cross-section as well as a four-sided trapezoidal transverse cross-section. However, as mentioned above, the extra sides or fluted edges taught by McGregor et al. are present to create thickness and to *further* improve tissue penetration (col. 3, lines 21-24), which does not necessarily teach away from having fewer sides. Since McGregor et al. do recognize that at the wider portion of the needle, there are six sides, and at the tapered end of the needle, there are only five sides which enable better tissue penetration, as well as a smaller wound area (col. 3, lines 15-20), it would occur to one of ordinary skill in the art to provide fewer sides if a thinner tapered needle is desirable. It would have been obvious to one of ordinary skill

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in the art at the time of invention to provide the desirable number of sides trapezoidal transverse cross-section with exactly four sides or the triangular transverse cross-section with exactly three sides, depending on the desired thickness and as long as the needle facilitates better tissue penetration, as well as a smaller wound area.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734